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APR 14 2008

510 (k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

The Assigned 510 (k) Number is: k070889

Submitter:	Wallac Oy Mustionkatu 6 20750 Turku, Finland Telephone: +358-2-2678 111 Fax: +358-2-2678 357
Contact Person:	Raija Koskivaara RA Manager raija.koskivaara@perkinelmer.com
Date of Summary Prepared:	March 27, 2008
Device Name:	AutoDELFIA Neonatal IRT L kit
Classification Name:	Chloride test system (21 CFR § 862.1170 / Product Code CGZ) Trypsin test system (21 CFR § 862.1725 / Product Code JNO)
Predicate Device:	AutoDELFIA Neonatal IRT kit 510(k) Number: K003668
Device Description:	The AutoDELFIA Neonatal IRT assay is a solid phase, two-site fluoroimmunometric assay based on the direct sandwich technique in which two monoclonal antibodies (derived from mice) are directed against two separate antigenic determinants on the IRT molecule. Standards, controls and test specimens containing IRT are reacted simultaneously with immobilized monoclonal antibodies directed against a specific antigenic site on the IRT molecule and europium –labeled monoclonal antibodies (directed against a different antigenic site) in assay buffer. The assay buffer elutes IRT from the dried blood spots on the filter paper discs. The complete assay requires only one incubation step. Enhancement Solution dissociates europium ions from the labelled antibody into solution where they form highly fluorescent chelates with components of the Enhancement Solution. The fluorescence in each well is the measured. The fluorescence of each sample is proportional to the concentration of IRT in the sample.

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Intended Use:

The AutoDELFIA Neonatal IRT L kit is intended for the quantitative determination of human immunoreactive trypsin(ogen) (IRT) in blood specimens dried on filter paper as an aid in screening newborns for cystic fibrosis using the 1235 AutoDELFIA ® automatic immunoassay system.

Substantial Equivalence:

The B022-112 AutoDELFIA Neonatal IRT L kit is compared to our currently marketed B055-112 AutoDELFIA Neonatal IRT kit (K003668) and is found to be substantially equivalent when considering the following similarities and differences between the two kits:

Similarities:

- The intended use is the same. They are both intended for the quantitative measurement of IRT in blood specimens dried on filter paper used as an aid in screening newborns for cystic fibrosis.
- The assay principle is the same. They are both based on the time resolved fluoroimmunoassay principle.
- They both use the same antibodies.
- The analytical performance characteristics of the two kits are equivalent.
- The distribution of IRT concentration in newborns is identical.

Differences:

- The main difference between the two kits is the matrix of kit standards and controls. The standards and controls in the B005-112 kit are dried blood spots on filter paper. In the B022-112 version of the kit the standards and controls are buffer based solutions, which are provided in the kit in the lyophilized form.
- To avoid a carry over effect of liquid standards and controls an extra flush step has been added to the assay procedure of the B022-112 kit.
- As stabilizers protease inhibitors have been added to standards and controls in the B022-112 kit.

The similarities and differences are also shown in the following table:

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	AutoDELFIA Neonatal IRT kit B005-112 (predicate device)	AutoDELFIA Neonatal IRT L kit B022-112
Intended use	Quantitative determination of IRT in blood specimens dried on filter paper as an aid in screening newborns for cystic fibrosis	Same
Assay principle	Time-resolved fluoroimmunoassay	Same
Assay Procedure	Standards and Controls on filter paper are punched into wells	Liquid Standards and Controls are dispensed into wells. Extra flush to avoid a carry over effect
Antibodies / Cross reactivity	Monoclonal antibodies derived from mice	Same
Standards	6 levels (Approx. values 0, 25, 50, 100, 250 and 500 ng/mL)	Same
Controls	3 levels (Approx. values 40, 70, 120 ng/mL)	Same
Standards and Control matrix	Blood spots on filter paper	Buffer based solutions lyophilized
Tracer	Anti-IRT-Eu tracer	Same
Assay Buffer	Neo IRT Assay Buffer	Same
Plates	Anti-IRT Microtitration Plates	Same
Precision (Total variation)	CV% 9.3 – 10.0	CV% 9.5 – 11.0
Limit of blank	< 4 ng /mL	0.18 ng/mL (95th %tile)
Linearity	Not given in the kit insert	Linear range 13 – 370 ng/mL
Hook effect	No effect found up to IRT conc. 40,000 ng/ mL	Same
IRT distribution in newborns	Mean: 27 ng/mL blood Median: 23 ng/mL blood 90th %tile: 42 ng/mL blood 94th %tile 50 ng/mL blood 95th %tile 52 ng/mL blood 96th %tile 55 ng/mL blood	Mean: 22 ng/mL blood Median: 18 ng/mL blood 90th %tile: 38 ng/mL blood 95th %tile 47 ng/mL blood 99th %tile 68 ng/mL blood

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 14 2008

Wallac Oy
Ms. Raija Koskivaara
Regulatory Affairs Manager
Mustionkatu 6, P.O. Box 10
20750 Turku, Finland

Re: k070889
Trade/Device Name: AutoDelfia® Neonatel IRT L Kit
Regulation Number: 21 CFR 862.1170
Regulation Name: Chloride Test System
Regulatory Class: Class II
Product Code: CGZ, JNO
Dated: April 04, 2008
Received: April 07, 2008

Dear Ms. Koskivaara:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070889

Device Name: AutoDELFIA® Neonatal IRT L kit

Indications For Use: The AutoDELFIA® Neonatal IRT L kit is intended for the quantitative determination of human immunoreactive trypsin (ogen) (IRT) in blood specimens dried on filter paper as an aid in screening newborns for cystic fibrosis using the 1235 AutoDELFIA® automatic immunoassay system.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K070889